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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,130	01/09/2001	Yoram Harth	P-1794-US	6520

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EXAMINER

JOHNSON, HENRY I

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/04/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,130

Applicant(s)

HARTH ET AL.

Examiner

Henry M Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/1/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-93 and 95-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-93 and 95-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Response to Arguments

Applicant's arguments filed August 1, 2003 as Supplement Amendment have been fully considered but they are not persuasive. The use of blue light in treating acne vulgaris is discussed in Sigurdsson V, et al., "Pharmacology and Treatment. Phototherapy of Acne Vulgaris with Visible Light", *Dermatology*, Vol 194, no. 3, 1997, pages 256-260, as cited in applicants Information Disclosure Statement. This establishes the basic treatment procedures and provides motivation for the modification of light devices to provide the treatment source.

Double Patenting - Nonstatutory

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51, 54, 65, 66, 67, 71-73, 82, 92, 93 and 106 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 9, 15, 21, 25-28 and 33 of co-pending Application No. 10/098592. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

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Claim 52 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The base claim has a spectral range from 405 to 440 nm. The spectral range of claim 51 is broader (405- 450).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 57, 58 and 102-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 57, it is not clear what is meant by delivered to multiple locations. This could be a large spot size over a large area, multiple fibers to multiple locations or moving the source to radiate on multiple locations.

Claim 58 recites the limitation "the head" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 58 recites the limitation "the face and the chin" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 102 recites the limitation "said at least one light source" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 103 recites the limitation "said at least one light source" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 104 recites the limitation "said at least one light source" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 82-85, 87, 88, 91, 95, 96 and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigurdsson V, et al., "Pharmacology and Treatment. Phototherapy of Acne Vulgaris with Visible Light", *Dermatology*, Vol 194, no. 3, 1997, pages 256-260 (hereinafter referred to as Sigurdsson). Sigurdsson discloses the treatment of acne vulgaris using several discrete wavelengths of visible light including, specifically, violet light with a spectral distribution of 400 to 450 nm (Fig. 2) that is delivered in a treatment regiment of three times weekly (plurality of discontinuous applications) for a total of 20 sessions with dosage of 20J/cm² per session. The violet light has substantially no UV radiation and Sigurdsson's tests indicated that UV was not necessary for a therapeutic effect and is discouraged due to the possibility of negative effects (page 259, Col. 2, lines 5-8). The results showed a reduced level of porphyrins in the acne lesions and suggest this causes photodynamic destruction of the acne.

Regarding claim 84, the reduction of the porphyrins is interpreted as due to the reaction as stated in the claim although Sigurdsson makes no specific reference to reaction with oxygen to produce peroxides, this result is implicit in that the radiation doses and times are the same.

Regarding claim 87, Sigurdsson teaches maintaining the maximum skin temperature below 41 °C (page 257, end of Col. 1).

Regarding claim 88, Sigurdsson discloses the use of a filter to remove UV from the violet light (page 257, Col. 1, paragraph 5).

Regarding claims 95 and 96, the treatment time is disclosed as 20 minutes per session.

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Claim 98 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sigurdsson. Sigurdsson discloses the treatment of acne on the face, back or chest, however does not disclose a quantitative area. Adult males would obviously have back or chest areas exceeding 200 cm².

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45, 46, 48-53, 55-64, 66-68, 70, 71, 74 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,843,143 to Whitehurst in view of U.S. Patent 6,223,071 to Lundahl et al. Whitehurst discloses a light source for biological treatment that may be a xenon, short arc, or metal halide lamp (Col 2, lines 6-8), incorporating a cylindrical reflector (abstract) and fiber bundle for delivery of the light to an area (Fig. 1, #15). Whitehurst discloses a light source with a wavelength tunable over the range of 350 to 700 nm. The tuning is accomplished using optical bandpass filters (Fig. 1, #s 8-12) that also narrow the bandwidth to less than 25 nm. Coatings are provided to filter the UV portion of the radiation (Col. 4, lines 12-13). Doses from 1 to 100 J/cm² are disclosed (Col. 5, line 59). Control of intensity is provided by movable louvers and a shutter is electrically activated to control the dosage. An electronic control is not disclosed. Lundahl teaches an illuminator for treating skin conditions with visible light, with 417 nm specifically cited. A microprocessor is included for monitoring and control of the illuminator. The use of computers in controlling medical radiation devices is pervasive and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a microprocessor as taught by Lundahl in the invention of Whitehurst

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to control the intensity and pulse duration during treatment. The limitation of a plurality of discontinuous applications is considered method of use, however, the device of Whitehurst as modified by Lundahl is capable of such operation.

Regarding claim 51, Whitehurst discloses an intensity of up to $9\text{W}/\text{cm}^2$ focused into a fiber optic (Col. 3, line 51). It is inherent that the intensity would remain above $40\text{ mW}/\text{cm}^2$ at a distance of 30 cm.

Regarding claim 53, the shutter of Whitehurst controls the duration of the radiation.

Regarding claims 55, 56 and 57, it is inherent the source is apart from the treatment area in Whitehurst as an optical fiber is used between the source and treatment area. It is further inherent that the fiber has at its distal end a handpiece that may be manually moved in relation to the treatment area.

Regarding claims 58 and 64, the intended area of use does not impact the structure of the apparatus.

Regarding claims 59 and 60, Whitehurst as modified by Lundahl teaches power densities of up to $9\text{W}/\text{cm}^2$.

Regarding claims 61, 62 and 63, the shutter of Whitehurst as modified by Lundahl is capable of opening for any period of time.

Regarding claim 66, Whitehurst discloses lenses and fiber optics as previously discussed.

Regarding claims 67, 68 and 79, Whitehurst teaches the use of a metal halide gas discharge lamp (Col. 2, line 6).

Regarding claims 70 and 71, Whitehurst discloses the use of reflectors (abstract) between the source and optical filter.

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Regarding claim 74, the microcontroller activated electronic switches of Lundahl (Col. 11, line 5) are interpreted as an integrated computer module.

Claims 47, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,843,143 to Whitehurst in view of U.S. Patent 6,223,071 to Lundahl et al as applied to claim 45 above, and further in view of Sigurdsson V, et al., "Pharmacology and Treatment. Phototherapy of Acne Vulgaris with Visible Light", Dermatology, vol 194, no. 3, 1997, pages 256-260. Whitehurst and Lundahl are discussed above, but do not disclose cooling the skin. Sigurdsson teaches the use of violet/blue light in treating acne that reduces the porphyrin content of the lesions. The treatment process includes maintaining the maximum skin temperature to between 40 and 41 °C. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a means for cooling the skin as taught by Sigurdsson in the invention of Whitehurst as modified by Lundahl to maintain the skin temperature at an acceptable and comfortable level.

Regarding claim 80, Sigurdsson discloses a significant improvement in skin condition using green light. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the green wavelengths as taught by Sigurdsson in the invention of Whitehurst as modified by Lundahl to take advantage of the deeper penetration afforded by this longer wavelength.

Claims 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,843,143 to Whitehurst in view of U.S. Patent 6,223,071 to Lundahl et al as applied to claim 45 above, and further in view of U.S. Patent 5,634,711 to Kennedy et al. Whitehurst as modified by Lundahl is discussed above, but does not teach the use of LEDs as a light source. Kennedy discloses a medical light emitting apparatus that uses blue (Col. 3, line 63) or red (Col. 4, line 3) LEDs. It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to use the LEDs as taught by Kennedy in the invention of Whitehurst as modified by Lundahl to achieve a reduction in size, heat generated and power consumed.

Claim 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson as applied to claim 82 above, and further in view of U.S. Patent 5,843,143 to Whitehurst in view of U.S. Patent 6,223,071 to Lundahl et al. Sigurdsson is discussed above, but does not disclose an apparatus with an integrated computer module. Whitehurst as modified by Lundahl discloses a light source as discussed above with a microprocessor module. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the apparatus with the microprocessor module as taught by Whitehurst as modified by Lundahl in the method of Sigurdsson to control the parameters of the process.

Claims 102 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson as applied to claim 82 above, and further in view of U.S. Patent 5,634,711 to Kennedy et al. All are discussed above. Sigurdsson discloses the use of violet and green radiation and Kennedy provides a source for such radiation using LEDs. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the light apparatus using LEDs as taught by Kennedy in the method of Sigurdsson to achieve the treatments with a cost effective, lower power device.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson as applied to claim 82 above, and further in view of U.S. Patent 5,843,143 to Whitehurst. All are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the gas discharge lamps as taught by Whitehurst in the method of Sigurdsson as a viable source of radiation at the required wavelength and intensity.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigurdsson. Sigurdsson teaches effective treatment of acne using violet and green light sources applied

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separately. Also disclosed is that application of full spectrum is less effective, therefore it would be obvious to use the two most effective wavelengths in a treatment regiment for acne.

Conclusion

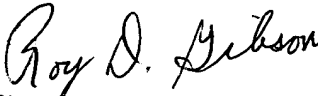
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Henry M Johnson, III
Patent Examiner
Art Unit 3739

Hmj


ROY D/GIBSON
PRIMARY EXAMINER